Re-evaluation Decision RVD2010-15

Tributyltin Compounds

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Re-evaluation Decision for Tributyltin Compounds

After a re-evaluation of the tributyltin compounds, Health Canada's Pest Management Regulatory Agency (PMRA) under the authority of the *Pest Control Products Act* and Regulations is proposing phase-out of products containing tributyltin compounds in Canada.

Tributyltin compounds consisting of tributyltin oxide (BTO) and tri-n-butyltin maleate (TBM) are actives which are under re-evaluation by Health Canada's Pest Management Regulatory Agency (PMRA). In Canada, the use of tributyltin compounds in antifouling paints was prohibited in 2002 (Special Review Decision SRD2002-01). The purpose of the current re-evaluation is to examine the remaining uses for these fungicides as material preservatives in textiles, leather, paper and wood.

An evaluation of available scientific information found that tributyltin compounds are classified as Track 1 substances under the federal Toxic Substances Management Policy (TSMP). The TSMP is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances (those that meet all four criteria outlined in the policy, i.e., CEPA-toxic or equivalent, predominantly anthropogenic, persistent (in one media) and bioaccumulative).

The PMRA's pesticide re-evaluation program considers potential risks, as well as the value of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the detail of the re-evaluation activities and program structure. Re-evaluation draws on data from registrants, published scientific reports, information from other regulatory agencies and any other relevant information available.

The regulatory approach regarding the re-evaluation of tributyltin compounds was first proposed in the consultation document[1] Proposed Re-evaluation Decision PRVD2010-11, *Tributyltin Compounds* (15 July 2010). This Re-evaluation Decision[2] describes this stage of the PMRA's regulatory process concerning the re-evaluation of tributyltin compounds and summarizes the Agency's decision, the reasons for it. The PMRA did not receive any comments during the consultation process. This decision is consistent with the proposed re-evaluation decision stated in Proposed Re-evaluation Decision PRVD2010-11, *Tributyltin Compounds* (15 July 2010). To comply with this decision, registrants of tributyltin products will be informed of the specific requirements affecting their product registration(s) and of the regulatory options available to them.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*

A detailed review of the persistence, bioaccumulation, and toxicity of tributyltin compounds in aquatic environments was conducted by Environment Canada[3] for non-pesticidal uses of these compounds. A Notice summarizing the scientific considerations of a final follow-up ecological assessment report[4] was published by Environment Canada in the *Canada Gazette*, Part 1, for Organotin Substances on August 8, 2009 under Section 68 of the *Canadian Environmental Protection Act* (CEPA) 1999. The report concluded that tributyltin compounds meet the TSMP Track 1 criteria for being:

- **Predominately anthropogenic**. Tributyltin compounds are present in the Canadian environment exclusively as a result of human activity. As such, tributyltin compounds are considered to have met the criteria of being predominately anthropogenic.

- **Persistent and Bioaccumulative**. Tributyltin compounds were observed to have half-life values in sediments up to 15 years exceeding the TSMP criterion for persistence in sediments (half-life $\geq$ 365 days in sediments). Tributyltin compounds have bioaccumulation factors (BAFs) ranging from 10 000 for marine periwinkles and oysters to 900 000 for freshwater mussels exceeding the TSMP criterion for bioaccumulation (BAF $\geq$ 5000). Tributyltin compounds meet criteria for persistence and bioaccumulation as defined by the *Persistent and Bioaccumulation Regulations* made under CEPA 1999.

- ***CEPA* –toxic**. Tributyltin compounds are harmful to aquatic organisms at low concentrations. They are entering, or may, enter the environment in a quantity or concentration or under condition that have or may have an immediate or long-term effect on the environment or its biological diversity. Therefore, tributyltin compounds meet the criterion under section 64 of CEPA 1999.

The proposed risk mitigation measures for non-pesticidal uses include addition of tributyltin compounds to the Virtual Elimination List (a prohibition regulation to be proposed under Section 93 of CEPA 1999).

For tributyltin uses regulated under the *PCPA*, the PMRA concluded that available information indicates that tributyltin compounds meet Track 1 criteria for persistence and bioaccumulation under the *Toxic Substances Management Plan* (TSMP). The PMRA also concluded that tributyltin compounds are toxic both on an acute and chronic basis to many aquatic organisms, including fish. These compounds are also highly toxic to molluscs, with chronic toxicity in oysters and clams occurring at fractional micrograms per litre concentrations.

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3 Review of the Persistence, Bioaccumulation and Toxicity of Tributyltin in Aquatic Environments in Relation to Canada's Toxic Substances Management Policy, R. James Maguire, Water Qual. Res. J. Canada, Volume 35, No. 4, 633-679.

4 Follow-up to the 1993 Ecological Risk Assessment of Organotin Substances on Canada's Domestic Substances List, Environment Canada 2009.

Consequently, under the authority of the *PCPA* and its Regulations, the PMRA has reached the decision to phase-out all remaining registrations for the sale and use of products containing these tributyltin compounds. This decision affects all end-use products containing tributyltin oxide (BTO) and tri-n-butyltin maleate (TBM) registered in Canada.

Other Information

Any person may file a notice of objection[5] regarding this decision on tributyltins within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA section of Health Canada's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#rrd), or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca)

Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2001-03, and the Special Review Decision SRD2002-01 can be found at www.healthcanada.gc.ca/pmra. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra.infoserv@hc-sc.gc.ca.

The federal TSMP and other Environment Canada reports are available through Environment Canada's website at www.ec.gc.ca/toxiques-toxics/.

The USEPA RED document for tributyltin compounds is available on the USEPA Pesticide Reregistration Status page at www.epa.gov/pesticides/reregistration/status.htm.

[5] As per subsection 35(1) of the *Pest Control Products Act*